



Substitute for form 1449A/PTO
(Modified)

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

Application Number	10/816,551
Filing Date	March 31, 2004
First Named Inventor	Barrett, Ronald W.
Art Unit	1614
Examiner Name	Not Assigned
Attorney Docket Number	459258-00039 (34545/US/4/RFT/SKS)

Sheet 1 of 4

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.	U.S. Patent Document Number-Kind Code* (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/JK/	A1	2,996,431	08-15-1961	Barry	
	A2	3,139,383	06-30-1964	Neville	
	A3	3,402,240	09-17-1968	Cain et al.	
	A4	3,811,444	05-21-1974	Heller et al.	
	A5	3,845,770	11-05-1974	Theeuwes et al.	
	A6	3,916,899	11-04-1975	Theeuwes et al.	
	A7	3,962,414	06-08-1976	Michaels	
	A8	3,992,518	11-16-1976	Chien et al.	
	A9	4,024,175	05-17-1977	Satzinger et al.	
	A10	4,066,747	01-03-1978	Capozza	
	A11	4,070,347	01-24-1978	Schmitt	
	A12	4,079,036	03-14-1978	Choi et al.	
	A13	4,083,949	04-11-1978	Bendikt	
	A14	4,093,709	06-06-1978	Choi et al.	
	A15	4,200,098	04-29-1980	Ayer et al.	
	A16	4,285,987	08-25-1981	Ayer et al.	
	A17	4,421,736	12-20-1983	Walters	
	A18	4,434,153	02-28-1984	Urguahart et al.	
	A19	4,721,613	01-26-1988	Urguahart et al.	
	A20	4,752,470	06-21-1988	Mehta	
	A21	4,816,263	03-28-1989	Ayer et al.	
	A22	4,820,523	04-11-1989	Shiohryn et al.	
	A23	4,853,229	08-01-1989	Theeuwes et al.	
	A24	5,563,175	10-08-1996	Silverman et al.	
	A25	5,698,155	12-16-1997	Grosswald et al.	
	A26	5,707,663	01-13-1998	Ayer et al.	
	A27	6,020,370	02-01-2000	Horwell et al.	
	A28	6,024,977	02-15-2000	Yatvin et al.	
	A29	6,103,932	08-15-2000	Silverman et al.	
	A30	6,117,906	09-12-2000	Silverman et al.	
	A31	6,171,615	01-09-2001	Roussin et al.	
	A32	6,310,098	10-30-2001	Guttuso, Jr.	
	A33	6,375,987	04-23-2002	Farah et al.	
/JK/	A34	6,379,700	04-30-2002	Joachim et al.	

Examiner Signature	/Jennifer M Kim/	Date Considered	7/31/2009
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				First Named Inventor	Barrett, Ronald W.
				Art Unit	1614
				Examiner Name	Not Assigned
Sheet	2	of	4	Attorney Docket Number	459258-00039 (34545/US/4/RFT/SKS)

U.S. PATENT DOCUMENTS					
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/JK/	A35	US App. No. 10/313,825		Bhat et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document Country Code ² Number ² Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁴
/JK/	B1	GB 2,362,646	11-28-2001	Bryans et al.		
	B2	EP 1,178,034 A1	02-06-2002	Bryans et al.		
	B3	EP 1,201,240 A2	05-02-2002	Bryans et al.		
	B4	WO 92/09560 A1	06-11-1992	Silverman		
	B5	WO 93/23383 A1	11-25-1993	Silverman et al.		
	B6	WO 97/29101 A1	08-14-1997	Horwell et al.		
	B7	WO 97/33858 A1	09-18-1997	Horwell et al.		
	B8	WO 97/33859 A1	09-18-1997	Horwell et al.		
	B9	WO 98/17627 A1	04-30-1998	Bryans et al.		
	B10	WO 99/08671 A1	02-25-1999	Guglietta et al.		
	B11	WO 99/21824 A1	05-06-1999	Bryans et al.		
	B12	WO 99/31057 A1	06-24-1999	Bryans et al.		
	B13	WO 99/31075 A1	06-24-1999	Bryans et al.		
	B14	WO 99/61424 A1	12-02-1999	Bryans et al.		
	B15	WO 00/15611 A1	03-23-2000	Bryans et al.		
	B16	WO 00/31020 A1	06-02-2000	Bellioti et al.		
	B17	WO 00/50027 A1	08-31-2000	Bryans et al.		
	B18	WO 01/90052 A1	11-29-2001	Bryans et al.		
	B19	WO 02/00209 A2/A3	01-03-2002	Bryans et al.		
	B20	WO 02/100347 A2	12-19-2002	Gallop et al.		
	B21	WO 02/100349 A2/A3	12-19-2002	Gallop et al.		
	B22	WO 02/28881 A1	04-11-2002	Gallop et al.		
	B23	WO 02/28411 A1	04-11-2002	Gallop et al.		
/JK/	B24	WO 02/28883 A1	04-11-2002	Gallop et al.		

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/JK/	B25	WO 02/32376 A2	04-25-2002	Gallop et al.	
/JK/	B26	WO 02/42414 A2/A3	05-30-2002	Gallop et al.	

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Citg No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			*#
/JK/	C1	ALDERMAN, "A Review of Cellulose Ethers in Hydrophilic Matrices for Oral Controlled-Release Dosage Forms," <i>Int. J. Pharm. Tech. & Prod. Mfr.</i> 1984, 5(3) 1-9.			
	C2	BAMBA et al., "Release Mechanisms in Gelforming Sustained Release Preparations," <i>Int. J. Pharm.</i> 1979, 2, 307.			
	C3	BRYANS et al., "3-Substituted GABA Analogs with Central Nervous System Activity: A Review," <i>Med. Res. Rev.</i> 1999, 19, 149-177.			
	C4	BRYANS et al., "Identification of Novel Ligands for the Gabapentin Binding Site on the $\alpha_2\delta$ Subunit of a Calcium Channel and Their Evaluation as Anticonvulsant Agents," <i>J. Med. Chem.</i> 1998, 41, 1838-1845.			
	C5	COLEMAN et al., "Polymer Review: A Practical Guide to Polymer Miscibility," <i>Polymers</i> 1990, 31, 1187-1231.			
	C6	DURING et al., "Controlled release of dopamine from a polymeric brain implant: in vivo characterization," 1989, <i>Ann. Neurol.</i> 25:351.			
	C7	FINCHER, "Particle Size of Drugs and Its Relationship to Absorption and Activity," <i>J. Pharm. Sci.</i> 1968, 57, 1825-1835.			
	C8	GEE et al., "The Novel Anticonvulsant Drug, Gabapentin (Neurontin), Binds to the $\alpha_2\delta$ Subunit of a Calcium Channel," <i>J. Biol. Chem.</i> 1996, 271, 5768-5776.			
	C9	GOLDBERG et al., "Transdermal Clonidine for Ameliorating Tamoxifen-Induced Hot Flashes," <i>J. Clin. Onc.</i> 1994, 12, 155-158.			
	C10	GOODSON, "Medical Applications of Controlled Release," <i>supra</i> , vol. 2, pp. 115-138 (1984).			
	C11	GUTTUSO et al., "Gabapentin's Effects on Hot Flashes in Postmenopausal Women: A Randomized Controlled Trial," <i>Obstet. Gynecol.</i> 2003, 101, 337-345.			
	C12	GUTTUSO, "Gabapentin's Effects on Hot Flashes in Hypothermia," <i>Neurology</i> 2000, 54, 2161-2163.			
	C13	HOES et al., "The Application of Drug-Polymer Conjugates in Chemotherapy," <i>Drug Carrier Systems</i> 1989, 9, 57-10			
	C14	JEFFERY et al., "Gabapentin for Hot Flashes in Prostate Cancer," <i>Ann. Pharmacother.</i> 2002, 36, 433-435.			
	C15	JEZKY et al., "Transpot of Pregabalin in Rat Intestine and Caco-2 Monolayers," <i>Pharm. Res.</i> 1999, 16, 519-526.			
	C16	KOURIEFS et al., "Hot Flashes and Prostate Cancer: pathogenesis and treatment," <i>British J. Urol. Int.</i> 2002, 89, 379-383.			
/JK/	C17	KRONENBERG et al., "Thermoregulatory physiology of menopausal hot flashes: a review," <i>Can. J. Physiol. Pharmacol.</i> 1987, 65, 1312-1324.			
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/JK/	C18	LANGER <i>et al.</i> , "Chemical and Physical Structure of Polymers as Carriers for Controlled Release of Bioactive Agents: A Review," <i>J Macromol. Sci. Rev. Macromol Chem.</i> 1983, 23:61.	
	C19	LANGER, "New Methods of Drug Delivery," 1990, <i>Science</i> 249:1527-1533.	
	C20	LEONG <i>et al.</i> , "Polymeric Controlled Drug Delivery," <i>Adv. Drug Delivery Rev.</i> 1987, 1, 199-233.	
	C21	LEVY <i>et al.</i> , "Inhibition of Calcification of Bioprosthetic Heart Valves by Local Controlled-Release Diphosphonate," <i>Science</i> 1985 228: 190-192.	
	C22	LOPRINZI <i>et al.</i> , "Megestrol Acetate for the Prevention of hot Flashes," <i>N. Engl. J. Med.</i> 1994, 331, 347-351.	
	C23	LOPRINZI <i>et al.</i> , "Pilot Evaluation of Gabapentin for Treating Hot Flashes," <i>Mayo Clin. Proc.</i> 2002, 77, 1159-1163.	
	C24	LOPRINZI <i>et al.</i> , "Venlafaxine in management of hot flashes in survivors of breast cancer: a randomized controlled trial," <i>Lancet</i> 2000, 356, 2059-2063.	
	C25	LU, "Dimensionless Presentation for Drug Release From a Coated Pure Drug Bead: 2 Experiment," <i>Int. J. Pharm.</i> , 1994, 112, 117-124.	
	C26	MAGNUS, "Nonepileptic Uses of Gabapentin," <i>Epilepsia</i> , (40) (Suppl. 6): S66-S72 (1999).	
	C27	QUELLA <i>et al.</i> , "Pilot Evaluation of Venlafaxine for the Treatment of Hot Flashes in Men Undergoing Androgen Ablation Therapy for Prostate Cancer," <i>J. Urol.</i> 1999, 162, 98-102.	
	C28	SAUDEK <i>et al.</i> , "A Preliminary Trial of the Programmable Implantable Medication System for Insulin Delivery," <i>N. Engl. J. Med.</i> , 1989, 321: 574.	
	C29	SEFTON, "Implantable Pumps," <i>CRC Crit Ref Biomed. Eng.</i> 14:201, 1987	
✓	C30	SHANAFELT <i>et al.</i> , "Pathophysiology and Treatment of Hot Flashes," <i>Mayo Clin. Proc.</i> 2002, 77, 1207-1218.	
/JK/	C31	VERMA <i>et al.</i> , "Osmotically Controlled Oral Drug Delivery," <i>Drug Dev. Ind. Pharm.</i> , 2000, 26:695-708.	

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